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10/068,812	02/04/2002	Richard J. Greff	034298-122	8436

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Thelen Reid & Priest LLP
P. O. Box 640640
San Jose, CA 95164-0640

EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/06/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, amendment, and request for extension of time, all filed 12/06/2004.

Claims 1-17 are included in the prosecution.

The following new ground of rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim1-15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment of the claims to recite "wetting agent solution" has introduced new matter to the scope of the claims that is not supported by applicant's disclosure as originally filed. Applicant disclosed on page 9 of the specification the wetting agents but no mention of the solution form. The text of the

specification that applicant is referring to for support on page 19 is actually a step in the process of preparing the composition wherein the cross-linked gelatin is soaked with solution of the wetting agent, then followed by the step of drying to obtain the final composition. Therefore, the final composition is not containing the solution of wetting agent as applicant recites in the claims.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1 and 5 a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, the broad ranges are "polymers and surfactants" and the narrow ranges are "polyoxyalkylenes, ether capped polyoxyalkylenes, ester capped polyoxyalkylenes, sorbitan esters, phosphatides, alkyl amines, and glycerin".

The following rejections were discussed in details in the previous office action, and are maintained for reasons of record:

Double Patenting

5. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,162,192, now on US '192, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 16 is directed to a kit comprises syringe, non-hydrated pledget consisting of cross-linked gelatin and wetting agent. The US '192 patent claims are directed to composition comprising syringe and pledget and hydrating agent. The difference between the present claims and the previously issued conflicted claim is that the issued claim does not teach the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '192, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable

expectation of having a sterile packaged composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claim 8 of the commonly assigned US '192 in view of US '061.

6. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-18 of U.S. Patent No. 6,200,328, now on US '328, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 16 is directed to a kit comprises syringe, non-hydrated pledget consisting of cross-linked gelatin and wetting agent. US '328 claims are directed to a system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating

agent as claimed by US '328, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '328 in view of US '061.

7. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 12-16 of U.S. Patent No. 6,440,151, now on US '151, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 16 is directed to a kit comprises syringe, non-hydrated pledget consisting of cross-linked gelatin and wetting agent. US '151 claims are directed to a system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is

advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '151, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '328 in view of US '061.

8. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 12-16 of U.S. Patent No. 6,527,734, now on US '734, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 16 is directed to a kit comprises syringe, non-hydrated pledget consisting of cross-linked gelatin and wetting agent. US '734 claims are directed to a system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and

hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '734, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '734 in view of US '061.

9. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-22 of U.S. Patent No. 6,540,735, now on US '735, in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 16 is directed to a kit comprises syringe, non-hydrated pledget consisting of cross-linked gelatin and wetting agent. US '735 claims are directed to system, reads

on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the previously issued conflicted claims is that the issued claims do not teach the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by US '735, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the issued claims 6-18 of the commonly assigned US '735 in view of US '061.

10. Claim 16 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-14, 17-22 of copending Application No. 10/366,752 in view of US 6,063,061 for Wallace et al., now on US '061. The present claim 16 is directed to a kit comprises syringe, non-hydrated pledget consisting of cross-linked gelatin and wetting agent. The potentially conflicted application claims are directed to system, reads on kit, comprising pledget and hydrating fluid and syringe. The difference between the present claims and the potentially conflicted claims is that the conflicted claims do not teach the pledget made of crosslinked gelatin. US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36). The reference teaches that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion (col.3, lines 5-7; col.8, lines 10-14). Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a hemostatic composition and kit comprising pledget and hydrating agent as claimed by the conflicted claims, and select crosslinked gelatin in a sterile package as disclosed by US '061, motivated by the teaching of US '061 that the non-hydrated crosslinked gelatin is advantageous because it swells to its full equilibrium swell value which is valuable in hemostasis and inhibiting tissue adhesion, with reasonable expectation of having a

packaged sterile composition or kit comprising non-hydrated crosslinked gelatin and hydrating agent that provide excellent hemostasis. Thus, the present claims are obvious over the conflicted claims of the commonly assigned application in view of US '061.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

11. Applicant's arguments filed 12/06/2004 have been fully considered but they are not persuasive. Applicants traverse the double patenting rejections by arguing that all the conflicting claims of the issued patents and copending application do not claim composition comprising pledget, hydrating agent and syringe

In response to this argument, the examiner position is that the kit of claim 16 is an obvious variant of the system claimed by all of the conflicted claims of the issued patents and copending application. The present claim 16 is directed to kit comprising pledget, syringe and wetting agent, and the system of the issued patent comprises compartment containing pledget and a hydrating fluid. Syringe means "an instrument for injecting or withdrawing fluid", according to WEBESTER II, and that reads on the compartment containing the pledget claimed in US '192. Therefore, the presently claimed kit is not patently distinct from any of the conflicted claims.

Claim Rejections - 35 USC § 102

12. Claims 1, 15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,063, 061 (061).

The present claim 1 recites composition comprising cross-linked gelatin and wetting agent that can be a polymer. The composition is in form of sterilized and packaged sponge (claim 15). Claim 16 recites kit comprising syringe, non-hydrated crosslinked gelatin and hydrating agent.

US '061 disclosed a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67; col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition can be in the form of sterile packaged kit comprising the non-hydrated gelatin and the hydrating agent that applied through a syringe (col.5, lines 6-10, 25-35; col.8, lines 32-36).

The limitations of claims 1, 15, and 16 are met by US '061.

Response to Arguments

13. Applicant's arguments filed 12/06/2004 have been fully considered but they are not persuasive. Applicant traverses this anticipatory rejection by arguing that the reference disclosed both hydrated and non-hydrated gel material. The kit includes a separate container with hydrating agent. The reference disclosed cross-linked gel rather than pledget.

In response to the above argument, the examiner position is the present claims are directed to composition and kit, and all the elements of the composition and kit are disclosed by the reference, i.e. cross-linked gelatin and plasticizer, which reads on the polymer cited by applicant as a wetting agent. The reference anticipates the present claims, in absence of support to the wetting agent solution. The expression "comprising"

of the claims language permits the presence of the hydrated gel and the container including the hydrating agent. The dried gel disclosed by the reference reads on the pledget since applicant did not define the pledget.

14. Claims 1-6, 8-13, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by US PGPB 2002/0042378 ('378) now US patent 6,706,690.

The present claim 1 recites composition comprising cross-linked gelatin and wetting agent. The claim recites the amount of the wetting agent intended to permit wetting of gelatin in the presence of an aqueous solution. The wetting agent is impregnated with (claim 2) or mixed with (claim 3) or coated on (claim 4) the gelatin. Claim 5 recites method for decreasing the hydration time of cross-linked gelatin composition comprises incorporating wetting agent with the gelatin prior to its hydration, i.e. prior to use, by mixing (claim 6), or coating the wetting agent into the gelatin (claim 8). The composition is bioabsorbable (claim 9). The composition further comprises : growth factor, thrombus enhancing agents or antimicrobial agents (claim 10). The wetting agent forms 0.1 to 10% of the gelatin (claim 11). Claim 12 recites the coating achieved by applying to the surface of the gelatin a solution consisting of the wetting agent and solvent in a concentration of 1-20%, then the solvent removed by evaporation of the solvent (claim 13). The composition is in form of sterilized and packaged sponge (claim 15).

PGPB '378 disclosed hemoactive material or composition that is suitable for inhibiting bleeding, i.e. hemostatic, and are delivered to the target region in the tissue

subject to bleeding (page 2: 0012; page 5: 0039). The material comprises cross-linked biologically compatible polymer, non cross-linked biologically compatible polymer, and plasticizer (abstract; page 2: 0016). The most preferred cross-linked polymer is gelatin (page 3: 0031; page 5: example 2). The non cross-linked polymers include cellulose derivatives, polyvinyl polymers, and polyoxyethylenes; and the plasticizers include polyethylene glycol and sorbitol (page 2: 0016, 0018), all disclosed by applicant in the first full paragraph of page 9 of the instant specification as wetting agents. The non cross-linked polymer solublizes when exposed to blood and releases the cross-linked polymer so that it can hydrate as it absorbs water from the blood, that reads on the intended function of the wetting agent (page 1: 0012). Decreasing the hydration time of the cross-linked gelatin that claimed in claim 5 is inherent in the material of the reference that comprises cross-linked gelatin and polyethylene glycol, and that has the wetting agent incorporated with the cross-linked gelatin prior to use and hydration. The cross-linked gelatin particles are dispersed in a solution comprising non cross-linked polymer and the polyethylene glycol and well mixed before drying as recited in claims 3 and 6; that also reads on impregnating the wetting agent with gelatin because the gelatin particles are suspended in the wetting agent as in claim 2; and reads on coating the wetting agent on the surface of gelatin because the particles of gelatin are surrounded by the suspension of the wetting agents as claimed in claims 4 and 8; and example 2 shows that the dispersion of the cross-linked and non cross-linked polymers and plasticizer is performed prior to the formation of the sponge, i.e. prior to foaming (page 1:0012; page 2: 0018; page 4: 0035; page 6: 0045). The cross-linked polymers

are degradable, i.e. bioabsorbable as claimed in claim 9 (page2: 0013). The composition further comprising bioactive agents including blood clotting agents such as thrombin, antibiotics, bacteriostatic and bacteriocidal agents, and antiviral, that reads on claim 10 (page 2: 0012; page 4: 0036). Example 2 of the reference shows that the amount of cross-linked gelatin in the composition is 1-4 grams, and the amount of polyethylene glycol is 0.1-2%, therefor, if the dispersion comprises 2 gm of gelatin that is to be 2000 mg in 100 ml and 1% of polyethylene glycol that is 100 mg per 100 ml, then the amount of polyethylene glycol is calculated to form 5 wt.% of the cross-linked gelatin, reads on the amount claimed in claim 11 (example 2: pages 5-6). The method of making the material of the reference includes dispersing the cross-linked gelatin particles in a solution comprising polyethylene glycol (wetting agents) in a concentration of 0.1-2% and well mixing the suspension before drying, i.e. before evaporating the solvent as in claims 12 and 13 (page 3: 0021; page 4: 0035; page 6: 0045).). The composition of the reference can be in the form of sponge (page 4: 0035) that is provided in sterile packs, as claimed in claim 15 (page 3: 0020).

The limitation of claims 1-6, 8-13 and 15 are met by PGPB '378.

Response to Arguments

15. Applicant's arguments filed 12/06/2004 have been fully considered but they are not persuasive. Applicant traverses this anticipatory rejection by arguing that the reference disclosed cross-linked polymer in dried non cross-linked polymer matrix, and does not teach wetting agent solution.

In response to this argument, the examiner position is that the claims are directed to composition and all the elements of the composition are disclosed by the reference. Applicant recites the wetting agents including polymer, hence, the non-cross linked polymer disclosed by the reference reads on the wetting agent. The reference disclosed on page 4, paragraph 0035 that the cross-linked gelatin is mixed with solution of non cross-linked polymer and then dried and that reads on the scope of the claims, absent support to the wetting agent solution in the final composition.

Claim Rejections - 35 USC § 103

16. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over PGPB '378.

The teaching of the PGPB '378 is discussed under 102 rejection above.

However, the reference does not teach impregnating the gelatin with the wetting agent as in claim 7, or the amount of the wetting agent in the gelatin composition after evaporation of the solvent.

It is expected that if the cross-linked gelatin is in the porous form, then the wetting agent is added to the porous material and mixed, the porous material will be impregnated with the wetting agent. Since applicant not claiming any particular form of the cross-linked gelatin, thus, mixing would read on impregnated depending on the form of the gelatin used in the instant invention.

It is expected to one having ordinary skill in the art to adjust the drying and evaporation of the solvent in order to obtain the desired concentration of the wetting

agent in the composition, and the claimed concentration of the wetting agent in claim 14 does not impart patentability to the claims, absent evident to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to obtain a composition comprising cross-linked gelatin and wetting agent as disclosed by PGPB '378 and select the method of incorporating the wetting agent into the gelatin such as mixing, impregnating or coating depending on the form of the cross-linked gelatin, and adjust the degree of drying of the final product to achieve a desired concentration of the wetting agent in the composition, with reasonable expectation of success having a hemostatic composition that stop bleeding at the site of application within a reasonable time.

17. With regard to the rejection of claims 7 and 14 under 35 U.S.C. 103(a) as being unpatentable over PGPB '378, applicant has failed to traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

GS Kishore
Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600
For TK Page